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| APPLICATION NO.                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/724,481                          | 11/28/2000  | Ross G. Clark        | P1071P1D15          | 7564             |
| 25213                               | 7590        | 10/07/2003           | EXAMINER            |                  |
| HELLER EHRMAN WHITE & MCAULIFFE LLP |             |                      | ROMEO, DAVID S      |                  |
| 275 MIDDLEFIELD ROAD                |             |                      | ART UNIT            |                  |
| MENLO PARK, CA 94025-3506           |             |                      | PAPER NUMBER        |                  |

1647

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |  |
|------------------------------|-----------------|--------------|--|
| <b>Office Action Summary</b> | Application N . | Applicant(s) |  |
|                              | 09/724,481      | CLARK ET AL. |  |
|                              | Examiner        | Art Unit     |  |
|                              | David S Romeo   | 1647         |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/28/00.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

Claims 1 and 2 are pending and being examined.

***Claim Rejections - 35 USC § 112***

5           The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10           The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

          Claims 1, 2 are indefinite over the recitation of “peptide is derived from a phage-displayed library” (claim 1, lines 3-4) because it is unclear if a peptide produced by a  
15   phage clone or peptide “derived” from a phage clone is intended. In the case of the latter, the nature and extent of the “derivation” are unclear. The metes and bounds are not clearly set forth.

          Claims 1, 2 are indefinite over the recitation of “a phagemid clone corresponding to the peptide” because use of the term “corresponding” makes it unclear if the phagemid  
20   clone displays “the peptide” or if the phagemid clone displays some variant of “the peptide.” The metes and bounds are not clearly set forth.

          Claims 1, 2 recite the limitation “serially diluting the phage” (claim 1, lines 6-7). There is a lack of antecedent basis for this limitation in the claim or the antecedent basis for “the phage” in this limitation is unclear. It is unclear if “the phage” is “a phagemid

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clone corresponding to the peptide,” or phage not “corresponding to the peptide.” The metes and bounds are not clearly set forth.

Claims 1, 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the  
5 steps. See MPEP § 2172.01. The omitted steps are: addition of the peptide or serially diluted phage. The active process steps in the claimed method comprise the following three steps:

1. incubating a phagemid clone, a polypeptide, and a ligand;
2. serially diluting the phage; and,
- 10 3. measuring the degree to which binding of the phagemid clone to the ligand is inhibited by the peptide.

Claim 1, line 8, recites “inhibited by the peptide,” which corresponds to step three, above. However, there is no earlier step in which “the peptide” is added. It is unclear if a peptide is added. The antecedent basis for “the peptide” is unclear. The  
15 metes and bounds are not clearly set forth.

Claims 1 and 2 are indefinite because they lack a process step which clearly relates back to the claim preamble and it is unclear what process is to be achieved; an intended use is not the same as achieving a result; in the absence of a recitation as to any result, or a process step producing a result, it is unclear what result of the process can be  
20 inferred.

Claims 1 and 2 recite the limitation “phage concentrations” (claim 1, lines 9-12). It is unclear if the “phage” in the phrase “phage concentrations” is the “phagemid” in the phrase “phagemid clone” or if the “phage” in the phrase “phage concentrations” is a

phage separate from the "phagemid" in the phrase "phagemid clone." The metes and bounds are not clearly set forth.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

5       The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10       Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For the purposes of this rejection, the "phage" in the phrase "phage  
15       concentrations" is interpreted as a phage separate from the "phagemid" in the phrase "phagemid clone." The phrase "a phagemid clone that is inhibited only at low phage concentrations" implies that the phagemid clone is not inhibited at high phage concentrations. In the case where the "phage" in the phrase "phage concentrations" is interpreted as a phage separate from the "phagemid" in the phrase "phagemid clone" it  
20       would be impossible for a phagemid clone to be inhibited only at low phage concentrations and not at high phage concentrations.

### ***Conclusion***

No claims are allowable.

25       ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

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IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

5        BEFORE FINAL        (703) 872-9306  
         AFTER FINAL        (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

10       CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

15



20       DAVID ROMEO  
         PRIMARY EXAMINER  
         ART UNIT 1647

DSR  
OCTOBER 6, 2003